2. Special 510(k) Summary K060314

Submitter: American Radiosurgery, Inc. (ARI)
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Phone number: (858) 451-6173
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Contact person: Franz Krispel
Date prepared: 2/6/06
Trade name: Rotating Gamma System, GammaART 6000
Common name: Gamma Knife, Gamma-ray Radiosurgery System, Nuclide Radiation Therapy System
Classification name: Radionuclide Radiation Therapy System
Substantial equivalence claimed to:
Predicate 510(k) Number K970647

Description:
This 510(k) Special Submission if for a modification to cleared K970647 Rotating Gamma System that has received a motion controller upgrade. The ACS SB214ND 4-axis motion controller (P/N: D-000024) has been replaced with the new Galil DMC-2000 5-axis motion controller (P/N: C-000141).

Basis for Submission:
The replacement of the RGS 6000 motion controller is a "control mechanism change" as specified by question B1 of the 510(k) Memorandum #K97-1 from the United States Food and Drug Administration, Office of Device Evaluation dated January 10, 1997. As this change can potentially "raise new issues of safety and effectiveness" (question B.8.3 from the FDA Guidance), a Special 510(k) has been submitted.

Intended use:
The Rotating Gamma System, GammaART 6000 is intended to be used by licensed Medical Professionals for radiation treatment of selected intracranial abnormalities, previously cleared for the OUR Rotating Gamma System and the Leksell Gamma Knife.

Summary of technological characteristics:
The Rotating Gamma System, GammaART 6000 is a tele-therapy device which contains 30 Cobalt-60 sources distributed on a hemispheric shielded source carrier. Inside the source unit is the "built in" secondary collimator which has four sides of collimators and one block position. When not treating, all sources are aligned with the block position of the secondary collimator, which in this case acts as a radiation shutter. Treatment starts with aligning the sources to the prescribed collimator size, then both the source unit and the secondary collimator rotate as one unit. By rotating the Cobalt-60 sources, 30 non-overlapping full 360 degree arcs are formed, resulting in high focal dose uniformity and small focal spot penumbra.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

American Radiosurgery, Inc.
c/o Mr. Daniel P. Olivier
President
Certified Software Solutions, Inc.
16787 Bernardo Center Drive, Suite A-1
SAN DIEGO CA 92128

Re: K060314
Trade/Device Name: Rotating Gamma System, GammaArt 6000
Regulation Number: 21 CFR §892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: February 6, 2006
Received: March 6, 2006

Dear Mr. Olivier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K060314

Device Name: Rotating Gamma System, GammaART 6000

Indications for Use:
The Rotating Gamma System, GammaART 6000 is a tele-therapy radiation treatment device intended to be used for stereotactic irradiation of intracranial structures. The device is to be used by licensed medical professionals, having been trained in the use and safety precautions of this device.

Prescription Use ✓ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060314